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The influence of long-term awareness of hyperlipidemia and of 3 years of dietary counseling on depression, anxiety, and quality of life☆,☆☆

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Abstract

Objective: The purpose of this study is to investigate the long-term effects of participation in a cardiovascular screening program and of dietary counseling on self-reported psychosocial outcomes and health concerns. **Methods:** High-risk subjects (n=563) with hyperlipidemia from the Oslo Diet and Antismoking Study (1972–1977) were reexamined after 25 years and randomly assigned to a new 3-year prospective 2×2 factorial placebo-controlled study in 1997 of n-3 polyunsaturated fatty acids and/or dietary counseling. Hospital Anxiety and Depression Scale (HADS), Life Satisfaction Index (LSI), and a new questionnaire on health concerns and behavior in response to risk information were collected at the 25-year follow-up. Hospital Anxiety and Depression Scale and LSI were evaluated at the end of the 3-year Diet and Omega-3 Intervention Trial on atherosclerosis (DOIT) in 505 subjects. **Results:** Twenty-five years after the screening program, HADS-anxiety was similar to the Norwegian norms (3.3 vs. 3.5), while HADS-depression was significantly lower (3.6 vs. 4.1, P<.01). Patients reported that 25 years of awareness of hyperlipidemia had influenced health concerns through a moderate change in diet habits, some restriction in life conduct, but an improvement of the total life situation. After a novel 3-year intervention in DOIT, there was no difference between the dietary counseling and control group with regard to anxiety, depression, or life satisfaction, but HADS-anxiety increased significantly (4.0 vs. 3.3, P<.001) in both groups. **Conclusion:** Compared to the general population, screening-positive subjects did not have increased mental distress 25 years after screening, and beneficial health behavior persisted. Dietary counseling did not affect psychosocial outcomes.

Keywords: Diet; Depression; Anxiety; Quality of life

Primary preventive measures based on the detection of risk factors are recommended for reducing cardiovascular mortality and morbidity [1]. Increased anxiety, distress, and altered health behavior are immediate reactions to an impending threat, and concerns have been raised on whether such reactions occur when risk factors are detected in screening programs [2]. If interventions are offered, the immediate reactions may be attenuated as the subjects have the ability to cope with the risk [2,3]. Studies with a longer follow-up indicate that these reactions do not persist, as there is no difference in anxiety between screening-positive and screening-negative individuals [2,4,5]. However, it is not

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known whether primary psychological reactions may be reinforced if the threat becomes more evident, particularly if relatives or friends get ill, as is expected with increasing prevalence of cardiovascular events among the elderly.

One type of intervention is dietary counseling, intending to determine the total intake of energy, including the amount of saturated and unsaturated fatty acids, through systematic interviews. Furthermore, through individual or group counseling, individuals with potentially unhealthy dietary habits are encouraged to modify them. Such counseling thus comprises both a nutritional and a psychosocial part. There is wide agreement on the favorable effect on cardiovascular risk factors [6], and current guidelines recommend individual dietary advice both as primary and as secondary prophylaxis [1].

Existing evidence supports a positive effect of comprehensive lifestyle interventions on quality of life (QOL) [7,8], possibly stronger in women [9]. Vizza et al. [10] reported clinically relevant effects on depressive symptoms and perceived stress of a 1-year intensive lifestyle program. However, it is possible that other components than dietary advice affect psychosocial outcomes [11], and we have not found other studies on the influence of dietary counseling alone on anxiety, depression, or QOL.

Our aims were to examine whether 25 years of awareness of high cardiovascular risk is associated with changes in symptoms of depression and anxiety compared to population norm data, and whether dietary counseling influences long-term perceptions of health behavior and concerns, depression, anxiety, or QOL.

Methods

Subjects

From a screening program of men aged 40 to 49 years, 1232 individuals with elevated cholesterol levels (>6.45 mmol/l) and systolic blood pressure <150 mmHg were recruited to the Oslo Diet and Antismoking Study in 1972 (Fig. 1) [12]. All participants received traditional lifestyle advice, including advice on cessation of smoking, and half the participants were randomized to 5 years of dietary counseling taking place in 1972 to 1977.

In 1997, all survivors (n=910) from the original population in the Oslo Diet and Antismoking Study were invited to participate in a new study, the Diet and Omega-3 Intervention Trial on atherosclerosis (DOIT). Altogether, 655 (72%) responded and were considered for inclusion (Fig. 1). There are no available psychosocial data on the patients not responding.

Exclusion criteria in DOIT were total cholesterol >8 mmol/l, blood pressure levels >170/100 mmHg, specific disease states or other practical causes thought to influence longevity or study compliance (cancer with short prognosis, end-stage renal failure, alcoholism, long travel distance), and unwillingness to discontinue n-3 polyunsaturated fatty acid (PUFA) supplementation before and during the trial period. A total of 92 patients were excluded or were unwilling to participate.

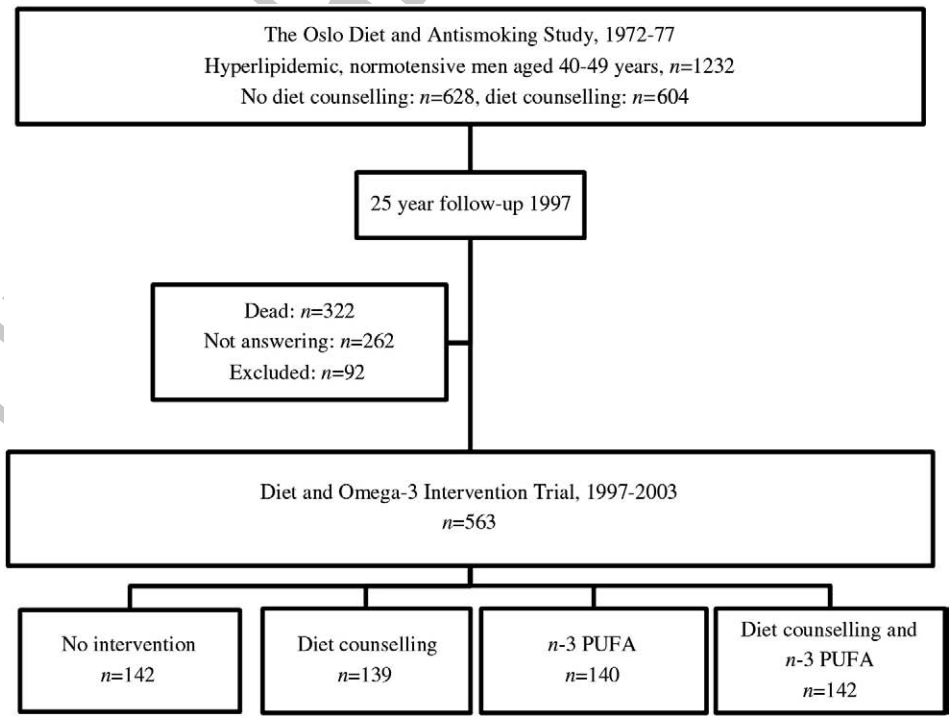

Fig. 1. The study design of the DOIT.

Study design

As the baseline examination of the novel 3-year DOIT was performed before the 563 participants were randomized, we considered this examination as a 25-year follow-up from the Oslo Diet and Antismoking Study. The DOIT was a 2×2 factorial-designed 3-year prospective study with n-3 PUFA and/or dietary counseling (Fig. 1). The groups were controls (no dietary counseling and placebo, n=142), diet only (dietary counseling and placebo, n=139), n-3 PUFA only (no dietary counseling and n-3 PUFA supplementation, n=140), and combined (dietary counseling and n-3 PUFA supplementation, n=142).

Intervention

All patients were informed that they were at increased risk of cardiovascular disease and given general lifestyle advice both at the start and at the end of the Oslo Diet and Antismoking Study. General lifestyle advice was also given to all participants prior to randomization at the baseline visit of DOIT. For the 281 subjects receiving dietary counseling, this was undertaken on an individual basis and consisted of the following: advice to increase the use of vegetable oils and margarines (rapeseed oil, olive oil, and sunflower oil), vegetables, fruit, and fish; advice to decrease the use of meat and fat from animal sources; advice to overweight subjects to adopt a calorie-restricted diet. The dietary counseling was given by a clinical nutritionist on the basis of a food frequency questionnaire [13] and was given for 30 to 45 min at baseline and after 3 months. The subjects visited the nutritionist every 6 months in the remaining study period. Compliance was monitored by the food frequency questionnaire and measurement of serum n-3 PUFAs, and additional follow-up was offered to subjects with poor compliance.

Data collection

To evaluate the influence of a previous lifestyle intervention on health concerns and perceived behavioral change, two (OE and EMH) of the authors constructed the "Awareness of Elevated Cholesterol" questionnaire. This is a new five-level Likert-item questionnaire with five questions in Norwegian, here given in direct translation:

"You were informed about having elevated cholesterol when you were about 40 years of age. To what degree has this influenced the following?

1. I have considered the risk of developing heart disease (0=Never, 4=All the time).
2. It has restricted my self-conduct (living more cautiously than I would otherwise have done) (0=Not at all, 4=Very much)
3. I have become more health conscious (0=Not at all, 4=Very much)
4. Participating in the Oslo Diet and Antismoking Study has caused me to alter my diet habits (0=Not at all, 4=Very much)
5. Overall, my awareness of having high cholesterol has caused my life situation to become (0=Much worse, 2=Unchanged, 4=Much better)"

Clinical data, blood tests, information concerning previous morbidity, medications, current smoking and alcohol habits, self-completed Hospital Anxiety and Depression Scale (HADS), and Life Satisfaction Index (LSI) were obtained at baseline and at the end of DOIT. Details of group assignment in the Oslo Diet and Antismoking Study were obtained to register whether the patients had dietary counseling in 1972 to 1977.

HADS is a 14-item questionnaire with seven items each on symptoms of anxiety (HADS-A) and depression (HADS-D), each ranging from 0 (*no problems*) to 3 (*maximum distress*) [14]. Its reliability and validity as a screening instrument have been confirmed by a multitude of studies [15]. Mean scores (S.D.) of HADS-A and HADS-D in a general Norwegian population of men aged 60 to 69 years are 3.5 (3.0) and 4.1 (3.1), respectively, and in men aged 70 to 79 years, 3.3 (3.0) and 4.4 (3.3), respectively [16].

Quality of life was measured by the 14-item LSI, which uses a Likert scale with each item ranging from 1 (*very satisfied*) to 4 (*very unsatisfied*) [17].

Questionnaires from individuals with up to two missing items on the HADS subscales, and up to four missing items on the LSI, were included in the analyses after simple imputation of the missing items. Nevertheless, 58 (10.3%) questionnaires were missing at baseline due to administration failure. Furthermore, we lack data from the final visit from an additional 99 participants, including 55 not attending this visit due to death or diseases and 44 not returning or completing the questionnaire. Subjects with missing data at baseline were ~~not~~ regarded as not eligible to be included in the intention-to-treat analyses. Q1

Statistics

Multiple linear regression analysis including items on the baseline HADS was used to create a model for estimating sum scores at the final visit for the 99 participants missing these. Within-group effects were tested with paired t tests or Wilcoxon rank test as appropriate. Between-group effects were tested with unpaired t tests or Mann–Whitney's test for data with normal distribution or skewed data, respectively. Q2

Univariate analysis of covariance (ANCOVA) was used to determine differences between intervention groups in change of the psychosocial parameters, with baseline values as covariates. The tests were performed according to the intention-to-treat principle. A 5% level of significance was used. SPSS 15.0 for Windows (SPSS Inc., Chicago, IL) was used for statistical analyses.

Ethics

The study was approved by the regional ethics committee, and all subjects gave their written informed consent prior to participation.

Results

The influence of 25 years of awareness of elevated cholesterol on psychosocial factors

Among screening-positive subjects participating in the Oslo Diet and Antismoking Study, the mean level (S.D.) of anxiety after 25 years was nonsignificantly lower and the level of depression was significantly lower than age- and gender-controlled Norwegians: 3.3 (2.7) vs. 3.5 (3.0) and 3.6 (2.7) vs. 4.1 (3.1), $P<.01$, respectively.

Table 1 presents scores on the Awareness of Elevated Cholesterol questionnaire. Literally, the average scorings for all the participants correspond to the following: seldom considerations of heart disease, some restriction in life conduct, little increase in health consciousness, a moderate to large change in diet habits, and, finally, some improvement in total life situation.

When comparing answers from the diet intervention and control groups in the previous interventional study in 1972 to 1977 (Table 1), patients with prior dietary counseling reported significantly more favorable health behavior, particularly concerning eating habits. They further reported an improved total life situation, but they more often considered the risk of heart disease and lived more cautiously.

The influence of a novel 3-year dietary counseling on psychosocial factors

The baseline demographic and clinical data in each group are presented in Table 2. The proportion of patients in each group who had previously received dietary counseling in 1972 to 1977 was 49% in the diet group and 51% in the nondiet group [not significant (ns)]. There was no significant difference between the groups at baseline. When applying standard risk stratification from the European guidelines on cardiovascular prevention, 372 subjects (73.6%) could be considered high-risk subjects at baseline. In addition, 58 (11.5%) of the subjects not fulfilling the high-risk criteria at the randomization were regular users of antihypertensives, aspirin, or statins. The 58 patients not included in the analyses had higher systolic blood pressure (153±20 vs. 148±18, $P<.05$) but otherwise similar baseline characteristics as the included patients.

Diet counseling attendance was satisfactory with 7% of the subjects needing additional follow-up. Furthermore, serum analyses showed significant lowering of saturated fat, increased ratio of polyunsaturated to saturated fat, and an increase in the intake of fiber in the diet intervention group [18].

Table 3 presents the measurements of anxiety, depression, and QOL at baseline and after 3 years for the dietary counseling and no-dietary counseling groups. There were no differences in the psychosocial parameters between the groups before the 3-year intervention.

Compared to a general population sample of Norwegian men aged 70 to 79 years, our patients reported significantly more anxiety (mean±S.D.: 4.0±2.9 vs. 3.3±3.0, $P<.001$) and nonsignificantly less depression (4.2±2.6 vs. 4.4±3.3, ns) at the end of DOIT. Thus, the estimated annual increase in score on HADS-A was significantly higher than in the general population. In addition, there was a significant increase in the proportion of participants with clinically relevant anxiety and depression (HADS ≥8), from 8% to 13% ($P<.05$) and from 9% to 13% ($P<.05$), respectively.

There were no differences between the diet and the nondiet groups in changes during the intervention period with respect to depression, anxiety, or QOL; yet, all variables showed significant negative within-group trends, except for LSI in the diet group (Table 3).

Discussion

The influence of 25 years of awareness of elevated cholesterol on psychosocial factors

We have shown that in a group of elderly men, who had been aware of their elevated cholesterol level for at least 25 years after participating in a screening program, there was no increase in the levels of symptoms of depression or anxiety compared with age- and gender-controlled Norwegians [16]. Our results support previous data from quantitative studies

Table 1
The influence of 25 years of awareness of elevated cholesterol on self-reported health concerns and behavior (0=*not at all*, 4=*very much*, mean±S.D.)

"Information about elevated cholesterol in my 40s has"	All (n=507)	No prior diet counseling[a] (n=249)	Prior diet counseling[a] (n=258)
1. Increased my concerns of heart disease	1.3±1.0	1.2±1.0	1.4±0.9**
2. Restricted my self-conduct	0.9±0.9	0.7±0.8	1.0±0.9**
3. Made me more health conscious	1.9±1.0	1.8±1.0	2.0±0.9**
4. Made me alter my eating habits	1.9±1.1	1.6±1.0	2.3±1.0***
5. Improved my total life situation	2.7±0.8	2.5±0.8	2.8±0.9***

Between-group t tests: **$P<.01$, ***$P<.001$.

[a] The Oslo Diet and Antismoking Study 1972 to 1977.

Table 2
Demographic and clinical characteristics at baseline of DOIT (n=505, mean±S.D. where appropriate)

Parameter	No diet counseling (n=252)	Diet counseling (n=253)
Age (years, range)	70 (64–75)	70 (65–75)
Previous cardiovascular disease (%)	28	27
Previous diabetes mellitus (%)	11	6
Treated hypertension (%)	27	25
Current smoking (%)	33	35
Alcohol (units/week)	5.2±7.0	5.2±8.2
Systolic blood pressure (mmHg)	148±18	149±18
Diastolic blood pressure (mmHg)	83±11	84±11
Pulse rate (per minute)	68±13	68±12
Body mass index (kg/m^2)	26.7±3.5	26.5±3.5
Total cholesterol (mmol/l)	6.3±1.0	6.2±1.1
HDL cholesterol (mmol/l)	1.4±0.4	1.4±0.4
LDL cholesterol (mmol/l)	4.1±1.0	4.0±1.0
Triglycerides (mmol/l)	1.7±0.9	1.7±0.9
Glucose (mmol/l)	6.1±1.7	5.9±1.1
High risk of cardiovascular disease (%)[a]	73	74

HDL=high-density lipoprotein; LDL=low-density lipoprotein.
[a] According to criteria by the European Cardiology Society.

and indicate that realization of own risk does not cause general psychological symptoms in a long-term perspective.

Bach Nielsen et al. [19] have approached this topic in a qualitative study with in-depth interviews and conclude that information emerging from screening programs needs to be communicated by physicians who know the patients well, this is in order to avoid undesirable psychological consequences and dropouts. In the Oslo Diet and Antismoking Study, advice was given by the same physician/nutritionist each time, with sufficient time for each consultation. In addition, the depth of follow-up may have contributed to a beneficial patient–physician relationship, improving compliance and limiting adverse psychosocial outcomes. Only 2.9% of the participants reported in 1977 that the screening program had caused anxiety [12].

Due to lack of available quantitative measures, we constructed a new questionnaire intending to obtain information concerning consequences of the patients' knowledge of elevated cholesterol. Although not comparable to other populations, our patients generally reported low levels of negative concerns, as well as an improved life situation. Interestingly, the patients receiving dietary counseling in the Oslo Diet and Antismoking Study reported somewhat more concerns about heart disease and a more restricted life conduct after 25 years. More importantly, they also reported significantly more beneficial eating habits than those not receiving such counseling, while both groups reported an improved total life situation. Thus, risk information and dietary advice raised appropriate concerns, without being perceived as distressing and without inducing clinical psychiatric symptoms, which we believe represent favorable health behavior.

Cautious interpretation of the data is essential due to inclusion bias and that the reported data are observational. Only elderly men were included, and although no formal psychiatric exclusion criteria were present, patients with depression and anxiety are often underrepresented in interventional studies with lifestyle modifications. There are no available data on psychosocial parameters for the patients not attending the 25-year follow-up in 1997, but the low prevalence of depressive symptoms at baseline may indicate that patients with depressive disorders are underrepresented. Such a selection bias would weaken our conclusion.

The influence of a novel 3-year dietary counseling on psychosocial factors

We found no differences in change of depression, anxiety, or QOL during the 3-year DOIT when comparing the nondiet and diet counseling groups. This is in contrast to previous studies showing beneficial psychosocial effects of lifestyle modifications as primary [7] or secondary prevention [8–10]. However, these studies used more comprehensive interventions, and our result may support that stress management, increased physical activity, or weight loss is more important for the favorable effect on mental distress and QOL than dietary counseling in such programs [11]. Alternatively, the lack of effect ~~of~~ on QOL in our study may be due to older participants than in comparable studies; unavoidable physical deterioration and increased incidence of noncardiovascular illnesses may have a much stronger influence on QOL than dietary counseling.

The increases in anxiety during the DOIT were significantly higher than in the general population. Post hoc analyses (data not shown) indicated that only the baseline level of anxiety was a predictor for this change,

Table 3
The influence of 3 years of dietary counseling on psychosocial parameters in elderly hyperlipidemic men (n=505, mean±S.D.)

	Baseline			36 months			Baseline—36 months
	No diet (n=252)	Diet (n=253)	P[a]	No diet (n=252)	Diet (n=253)	P[a]	P, ANCOVA
HADS-anxiety	3.4±2.7	3.2±2.6	ns	4.0±2.9**	3.9±3.0***	ns	ns
HADS-depression	3.7±2.8	3.4±2.7	ns	4.3±2.5**	4.1±2.8***	ns	ns
LSI	24.2±4.8	23.9±5.1	ns	24.7±4.4	24.0±5.2	ns	ns

~~*P<.05,~~ **P<.01, ***P<.001 (within-group change, Wilcoxon test).
[a] Between-group test, Mann–Whitney.

while depression, previous morbidity, previous dietary counseling, and current interventional strategy had no effect. Possible explanations include that the age-dependent effect of worsening somatic health develops faster in high-risk populations. Alternatively, participation in such a study with renewed focus on cardiovascular risk could affect psychosocial parameters negatively. However, we consider this to be unlikely, as we would then have expected lower QOL.

The results may have been biased by missing data. The statistical models used for estimation of missing data at the 36-month visit were based on data from the attending patients. Those patients not attending the final visit due to poor somatic health might have reported more depression, anxiety, and worse QOL. However, as the proportion of patients receiving dietary counseling among those not attending the final visit was 52%, we believe that this would not have any major influence on the main results of the interventions. The unavoidable open design with regard to diet counseling might have weakened the effect on the outcomes, as participants in the control group attended visits with the same frequency and thus probably gave more attention to lifestyle. Even so, data on compliance implies that the diet group differed significantly from the control group [18].

Although limited to a population of elderly men with hyperlipidemia and without serious psychiatric comorbidity, our study suggests that focus on cardiovascular risk factors and dietary counseling can be recommended without risk of inducing psychosocial stress. This is a population where dietary habits may not be in focus in daily life due to sociocultural factors and gender roles. We believe that the simple dietary counseling performed in our study is applicable in primary care, either by general physicians or by clinical nutritionists. Considering the relatively high compliance and moderate but significant beneficial outcomes of dietary advice shown in the present studies [18,20] and in reviews [6], it is of clinical importance that dietary counseling can be recommended to a larger public. In future studies, there may be a stronger focus on psychosocial factors among nonresponders and patients not willing to participate.

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